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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 811,789	01 12/2001	Yong-Jun Lee	3138.FLK	2186

26304

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09/29/2003

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EXAMINER

TELLER, ROY R

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/811,789

Applicant(s)

LEE ET AL.

Examiner

Roy Teller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 12 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

This office action is in response to the instant specification, filed 1/12/01.

Claims 1-19 are pending.

#### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ho (USPN 5,109,117).

The claimed invention is drawn to a process for preparing biologically active somatotropin from inclusion bodies of a recombinant host cell containing an inactive form of somatotropin protein, which comprises the steps of: (a) contacting the inclusion bodies with an aqueous alcohol solution at an alkaline pH to solubilize the protein; and (b) bringing the solubilized protein into contact with a mild oxidizing agent to refold and form intramolecular disulfide bonds between cysteine residues of the protein.

Ho teaches a method for the solubilization and naturation of somatotropin from refractile bodies produced by r-DNA technology wherein the refractile bodies are dissolved in an aqueous solution comprising a chaotropic agent such as urea or guanidine hydrochloride and a soluble

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organic alcohol such as isopropanol or benzyl alcohol (see abstract). Ho discloses The solubilized protein is exposed to mild oxidation for a time sufficient to allow the protein to form disulfide bonds and refold to its native conformation (see abstract). Ho teaches that the presence of the alcohol suppresses the formation of somatotropin dimmers and aggregates and results in higher yields of the desirable monomeric form of the protein (see abstract). Ho discloses that by "refractile bodies" is meant the inclusion bodies or cytoplasmic aggregates containing, at least in part, the heterologous protein to be recovered (see column 2, lines 54-56). Ho teaches the alcohol is present in an amount of from about 1 to 10% volume (see column 8, claim 4). Ho discloses the pH of the solution is above about 9 (see column 8, claim 9). Ho teaches said somatotropin is bovine or porcine (see column 8, claim 10). Ho discloses said organic alcohol is isopropanol (see column 8, claim 12). Ho teaches a mild oxidizing agent such as air (see column 2, line 8). Ho does not teach the use of avian or fish somatotropin.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have used the method of Ho in order to solubilize somatotropin protein from refractile bodies of host cells containing the protein. While Ho does not teach the method without the use of urea, absent some evidence to the contrary, the method disclosed by Ho would inherently possess this property. Ho discloses that these and other variations of the present invention will be readily apparent to those skilled in the art (see column 7, lines 13-14).

It is noted that claims 1-19 are drawn to a product-by-process. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the

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prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe* 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985) (MPEP 2113).

***Conclusion***

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703)305-4243. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

RT  
1654  
9/26/03

RT



CHRISTOPHER R. TATE  
PRIMARY EXAMINER